

INEX.P-006
PATENT APPLICATION

What is claimed is:

1 1. An immunostimulatory composition comprising a nucleic acid polymer
2 encapsulated in a lipid particle comprising a cationic lipid.

1 2. The composition according to claim 1, wherein the nucleic acid
2 polymer is a non-sequence specific immunostimulatory oligodeoxynucleotide sequence.

1 3. The composition according to claim 1, wherein the nucleic acid
2 polymer includes at least one CpG motif.

1 4. The composition according to claim 1, wherein the nucleic acid
2 polymer has no detectable immunostimulatory activity in the mammal in the absence of the
3 lipid particle.

1 5. The composition according to claim 1, wherein the nucleic acid
2 polymer consists of deoxynucleotide residues joined by phosphodiester linkages.

1 6. The composition according to claim 1, wherein the cationic lipid is
2 selected from the among DODAP, DODMA, DMDMA, DOTAP, DC-Chol, DDAB,
3 DODAC, DMRIE, DOSPA and DOGS.

1 7. The composition according to claim 1, wherein the lipid particle further
2 comprises an exchangeable steric barrier lipid.

1 8. The composition according to claim 7, wherein the exchangeable steric
2 barrier lipid is a PEG-lipid, a PAO-lipid or a ganglioside.

1 9. The composition according to claim 1, further comprising a drug or
2 cytotoxic agent.

1 10. The composition of claim 9, wherein the drug or cytotoxic agent is
2 associated with the lipid particle.

1 11. The composition according to claim 1, further comprising an antigenic
2 molecule selected from among polypeptides, proteins, glycolipids and glycopeptides
3 comprising at least one epitope of the target antigen and nucleic acids encoding at least one
4 epitope of the target antigen.

1 12. The composition according to claim 11, wherein the antigenic molecule
2 is associated with the lipid particle.

1 13. The composition according to claim 12, wherein the nucleic acid
2 polymer is a non-sequence specific immunostimulatory sequence.

1 14. The composition according to claim 11, wherein the nucleic acid
2 polymer includes at least one CpG motif.

1 15. The composition according to claim 11, wherein the nucleic acid
2 polymer has no detectable immunostimulatory activity in the mammal in the absence of the
3 lipid particle.

1 16. The composition according to claim 11, wherein the
2 oligodeoxynucleotide consists of deoxynucleotide residues joined by phosphodiester linkages.

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1 17. The composition according to claim 11, wherein the cationic lipid is
2 selected from the among DODAP, DODMA, DMDMA, DOTAP, DC-Chol, DDAB,
3 DODAC, DMRIE, DOSPA and DOGS.

1 18. The composition according to claim 11, wherein the lipid particle
2 further comprises an exchangeable steric barrier lipid.

1 19. The composition according to claim 17, wherein the exchangeable
2 steric barrier lipid is a PEG-lipid, a PAO-lipid or a ganglioside.

1 20. A method for stimulating cytokine secretion in a mammal comprising
2 administering to the mammal a composition comprising a nucleic acid polymer encapsulated
3 in a lipid particle in an amount effective to stimulate cytokine secretion.

1 21. A method for inducing an immune response to a target antigen,
2 comprising the step of administering to the mammal a composition comprising
3 a nucleic acid polymer encapsulated in a lipid particle comprising a cationic
4 lipid; and

5 an antigenic molecule selected from among polypeptides, proteins, glycolipids
6 and glycopeptides comprising at least one epitope of the target antigen and nucleic acids
7 encoding at least one epitope of the target antigen, said antigenic molecule being mixed,
8 associated or co-administered with the lipid particle,
9 said composition being administered in an amount effective to induce an immune response to
10 the target antigen.